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Stable compsns. of human B cell differentiation factor - contg. serum-derived proteins such as albumin or alpha 2-macroglobulin as solubilising or stabilising agent

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Abstract (Basic): JP 3027320 A

Stabilised pharmaceutical compsns. of human B cell differentiation (human BCDF) are suitable for admin. to animals and humans. Human BCDF in the compsns. contain an amino acid sequence contg. 200 residues, where Ala may be present. Human BCDF does not have sugar chains, and is made of procaryotes. Therapeutically effective amt. of human BCDF is dissolved or dispersed in insol. carrier medium contg. at least one solubilising or stabilising agent. The compsns. are in the form of liq. or a lypholisate. The solubilising or stabilising agent is one of the serum-derived proteins, such as albumin or alpha-macroglobulin.

USE/ADVANTAGE - The pharmaceutical compsns. having a therapeutically effective amt. of BCDF, which can differentiate matured B cells into antibody-producing cells, are useful as a stabilised pharmaceutical formulation suitable to administer to animals or humans.

In an example, recombinant DNA technique using E. coli produced natural human BCDF contg. the N-terminal Ala was employed. 50 micro-1 of 20% human serum albumin liq. (contg. Na 3.3mg/ml, Cl 3.1mg/ml, Na caprylate 2.659mg/ml, acetyltryptophane Na 4.2925m/ml) was added to 200 micro-1 of the human BCDF (200 micro-g/ml PBS soln., specific activity 2.5 U/ng). The total amt. was made to 41 by adding saline and aseptically filtered through 0.22 micron Millipore filter. The filtrate (200 micro-1, contg. 2 micro-g human BCDF and 500 micro-g human serum albumin) was placed in a 15 x 33mm sterilised glass vial and lypholised at 30m toll and 10 deg.C. for 20 hrs.. The lypholisate retained 100 15% activity after storage for 7 months at under 20 deg.C.. (7pp Dwg.No.0/0)

Title Terms: STABILISED; COMPOSITION; HUMAN; CELL; DIFFERENTIAL; FACTOR; CONTAIN; SERUM; DERIVATIVE; PROTEIN; ALBUMIN; ALPHA; MACRO; GLOBULIN; SOLUBLE; STABILISED; AGENT

Derwent Class: B04; C03; D16

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